UNITED STATES DEPARTMENT OF COMMERCE
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MV

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/219,442	12/23/98	HU J	PF112P2D1

022195
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HM22/0309

EXAMINER	
SAOUD,C	
ART UNIT	**PAPER NUMBER**
1646	10

DATE MAILED: 03/09/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/219,442	Applicant(s) HU et al.
	Examiner SAOUD	Group Art Unit 1646

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 15 Dec. 1999.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1, 22-24, 26-346 is/are pending in the application.

Of the above claim(s) 1, 22-24, 26-32, 45-52, 65-72, 85-92, 105-112, 125-132, 157-164, 177-184, 197-204, 217-224, 237-244, 257-264, 277-284, 297-304, 318-325, 339-346. is/are withdrawn from consideration.

☐ Claim(s) 33-44, 53-64, 73-84, 93-104, 113-124, 133-156, 165-176, 185-196 is/are allowed.

☒ Claim(s) 205-216, 225-236, 245-256, 265-276, 285-296, 305-317, 326-338 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2, 8, 9

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

DETAILED ACTION

Status of Claims

1. Claims 2-21 and 25 have been canceled and claims 33-346 have been added as requested in the amendment of paper #7, filed 15 December 1999. Claims 1, 22-24, and 26-346 are pending in the instant application.

Election/Restriction

2. Applicant's election with traverse of Group II in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the search of the polypeptide claims would provide useful information for Groups I and III-XII, thus the searches would be overlapping. This is not found persuasive because an application may properly be required to be restricted to one of two or more claimed invention if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04 (j)) or distinct (MPEP § 806.05 - § 806.05(i)). The Examiner has shown that the inventions of Groups I and II are distinct for the reasons in the previous Office action (see paper #6). Furthermore, M.P.E.P. § 803 provides that the separate classification (i.e., class and subclass) of distinct inventions is sufficient to establish a *prima facie* case that the search and examination of the plural inventions would impose a serious burden upon the Examiner; such separate classification was set forth in the Office action mailed 15 Nov. 1999 (Paper #6). Applicant has offered no evidence to rebut this showing. Applicant's arguments that "authors also routinely include a description of the polynucleotides and antibodies" and that "the searches

for Groups I-XII would be overlapping" is not persuasive because the searches for each group are not coextensive as indicated by their separate classification. Therefore, a *prima facie* case for a serious search burden was presented in paper #6 and Applicant has offered no evidence to rebut this showing.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1, 22-24, 26-32, 45-52, 65-72, 85-92, 105-112, 125-132, 157-164, 177-184, 197-204, 217-224, 237-244, 257-264, 277-284, 297-304, 318-325, 339-346 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 8.

EA 3/7/00

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 73-84, 93-104, 113-124, 245-256, 285-296, and 326-338 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention appears to employ novel vectors and/or microorganisms. Since the microorganism is essential to the claimed invention it must be obtainable by a repeatable method set

forth in the specification or otherwise be readily available to the public. The claimed plasmids' sequences are not fully disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. The enablement requirements of 35 USC § 112 may be satisfied by a deposit of the plasmid and/or microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the DNA sequences and/or microorganism are readily available to the public. Accordingly, it is deemed that a deposit of these plasmids and/or microorganisms should have been made in accordance with 37 C.F.R. 1.801-1.809.

It is noted that applicants have deposited the organism but there is not indication in the specification as to public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become inviable.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 33-44, 53-64, 73-84, 93-104, 113-124, 133-156, 165-176, 185-196, 205-216, 225-236, 245-256, 265-276, 285-296, 305-317, and 326-338 are rejected under the judicially created doctrine of double patenting over claims 1-60 of U. S. Patent No. 5,932,540 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a purified protein having the amino acid sequence of SEQ ID NO:2 or 4 or a protein encoded by the cDNA contained in ATCC Deposit No. 75968 or 97149, or various fragments thereof. The instant claims rely on the method of production of the protein, however, these methods were

disclosed in the parent application which matured into U. S. Patent No. 5,932,540. The product by process claims were not restricted from the product claims, therefore, a double patenting rejection is appropriate since what is being claimed and what is patented is the same protein.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 8AM to 3PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 7, 2000

CHRISTINE SAOUD
PATENT EXAMINER
Christine Saoud